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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/326,502	06/04/1999	STEWART M. KROLL	COUL-005/04U	4274

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EXAMINER

CLOW, LORI A

ART UNIT

PAPER NUMBER

1631

DATE MAILED: 08/26/2003

24

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/326,502

Applicant(s)

KROLL ET AL.

Examiner

Lori A. Clow, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 June 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 2, 4-20, 22-24, 83 and 84 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 4-20, 22-24, 83, and 84 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Applicants' arguments, filed 13 June 2003, have been fully considered by they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claims 1, 2, 4-20, 22-24, 83, and 84 are currently pending.

Claims Rejections-35 USC 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 2, 4-20, 22-24, 83, and 84 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wahl et al. (WO 96/34632 A1) in view of US 6,251,362 B1 (Wahl et al.).

Applicant asserts that the instant invention is distinguishable from Wahl et al. because a clearance profile is established to determine the optimally effective patient-specific therapeutic dose. However, Wahl et al. absolutely considers the clearance profile in the invention of WO 96/34632 A1. Page 5, lines 6-17 clearly explains the importance of determining the rate of clearance or disappearance of radioactivity from a patient. This step determines changes in the radiation concentration of a particular patient over a given period of time, clearly meeting the limitations of claim 1.

'632 specifically teaches total body dose (TBD) at page 6, lines 7-8, page 18, lines 17-22, and page 22, beginning line 17. '632 also teaches activity hours at page 10, lines 26-30 and residence times calculations on at least page 5, lines 18-30 and page 6, lines 1-20. Maximum tolerated doses are described in the example on page 28 (dose escalation studies). '632 also teaches, at page 18, steps 7 and 8, cross-indexing the effective half-life and teach, at page 33,

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claims 12 and 13, that the method of establishing the maximal effective dose requires the cross-indexing to assess half-life values.

Applicant further argues that the dependent claims have been ignored. However, Wahl et al. teaches the aspects of the dependent claims as follows: Claim 2 is taught in the Example 2, at page 28. Claim 4 is taught at numerous places in the specification, including page 22, beginning line 17. Height and gender, as in claim 5, are taught in the formula at page 25, line 28. Clearance studies of claim 6 are taught at page 19. Claim 7 is taught in Example 2 at page 28. The activity time shape curve of claim 8 is taught at least at pages 10-11. Claim 9 is taught at page 19 (clearance rate section). Claims 10 and 22 are taught at least at Figures 5 and 6. Claim 11 is taught at page 21, line 14. Claims 12 and 17 are taught in Figure 4, where at least 7 time points are taken. Measurements at various time points are taken as in claims 13 and 24 at page 20 and residence time is calculated at page 21. Background is corrected, as in claims 14, 16, and 23 at page 21. Claim 15 is taught at pages 20-22. Claim 18 is taught at page 11, lines 20-24. The radiopharmaceutical used can include a ^{131}I -labeled anti-B1 antibody, as taught at page 3, line 10, as in claims 83 and 84.

WO 96/64632 does not specifically recite all of equations of the instant specification. However, US 6,251,362 B1 does outline the equations indicated in the instant claims. For example, total body dose equation is at column 10, line 5; residence time is shown at column 9, line 60; activity is described by the equation at column 6, line 60. US 6,251,362 B1 also illustrates in Figures 1-7j, 8e-h, and 10 the various implementations of the equations to establish a patient-specific therapeutic dose. It would have been prima facie obvious to combine the

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teachings of WO 96/64632 and US 6,251,362 B1, the motivation being that quantitation of results using specific equations is suggested by '632 in numerous paragraphs.

Applicant argues that the operations set forth in the claims, particularly claim 1, are not addressed by the examiner, the specification of WO 96/34632 repeatedly states that individual equations could be solved **manually** and that it is only preferred to represent them graphically, as done in the specification (see page 27, lines 10-12), thus making it obvious to put into equations or algorithms to practice the invention.

No claims are allowed.

Conclusions

Claims 1, 2, 4-20, 22-24, 83, and 84 are currently pending.

The rejections under 35 U.S.C. 112, second paragraph have been withdrawn.

The rejections under 35 U.S.C. 102(b) have been withdrawn.

Newly made rejections under 35 U.S.C. 103(a) have been applied.

Inquiries

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The CM1 Fax Center number is either (703) 308-4242, or (703) 308-4028.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lori A. Clow, Ph.D., whose telephone number is (703) 306-5439. The examiner can normally be reached on Monday-Friday from 10am to 6:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael P. Woodward, Ph.D., can be reached on (703) 308-4028.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Legal Instrument Examiner, Tina Plunkett, whose telephone number is (703) 305-3524, or to the Technical Center receptionist whose telephone number is (703) 308-0196.

August 21, 2003
Lori A. Clow, Ph.D.
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Lori A. Clow

MARJORIE MORAN
PATENT EXAMINER

Marjorie A. Moran